DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2014

NovaBone Products, LLC
Ms. Lisa Simpson
Manager, Regulatory Affairs
13510 Northwest U.S. Highway 441
Alachua, Florida 32615

Re: K140946
Trade/Device Name: NovaBone MacroFORM BIOACTIVE – Packable Graft
NovaBone MacroFORM BIOACTIVE – Moldable Composite
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: August 1, 2014
Received: August 5, 2014

Dear Ms. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140946

Device Name
NovaBone MacroFORM - BIOACTIVE Packable Graft, NovaBone MacroFORM - BIOACTIVE Moldable Composite

Indications for Use *(Describe)*
NovaBone MacroFORM bone graft devices are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone MacroFORM is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NovaBone MacroFORM must be hydrated with autogenous bone marrow prior to implantation. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
MacroFORM BIOACTIVE

Date Prepared: **August 14, 2014**

510(k) Holder / Submitter:

Name:	NovaBone Products, LLC
Address:	13510 NW US Highway 441
	Alachua, FL 32615
Telephone:	(386) 462-7661, ext 216
Fax:	(386) 462-7525
Contact:	Lisa Simpson / Manager, Regulatory Affairs

Name of Device:

Trade Names:	NovaBone MacroFORM – BIOACTIVE Packable Graft
	NovaBone MacroFORM – BIOACTIVE Moldable Composite
Common Name:	Osteoconductive Bone Void Filler
	Synthetic Resorbable Bone Graft Material
Regulation Number:	21 CFR 888.3045
Regulation Name:	Bone Void Filler
Regulatory Class:	Class II
Product Code:	MQV

Legally Marketed Predicate Devices:

K090731 / K060432	NovaBone Porous – Synthetic Bone Graft Scaffold
K083033	Orthovita Vitoss Foam Bone Graft Substitute

510(k) SUMMARY
MacroFORM BIOACTIVE

Device Description

NovaBone MacroFORM is an osteoconductive bioactive device used for grafting osseous defects. It is a composite of bioactive calcium-phospho-silicate granules and a collagen binder. The bioactive particulate is composed solely of elements that exist in normal bone (Ca, P, Na, Si, O). The collagen binder consists of bovine collagen. When mixed with bone marrow aspirate, the device forms a non-hardening graft that is applied directly to the intended graft site. The device is slowly absorbed during graft site healing.

During absorption of the collagen binder, the particulate material remaining undergoes a time-dependent kinetic modification of the surface to stimulate osteoblast activity and guide the formation of bone across the graft site. Specifically, a series of surface reactions on the particles results in the formation of a calcium phosphate layer that is substantially equivalent in composition and structure to the hydroxyapatite found in bone mineral. This apatite layer provides scaffolding onto which the patient's new bone will grow, allowing complete repair of the defect. During healing, the graft particulate is absorbed and remodeled into new bone.

MacroFORM is provided in three basic forms: loose granules, a composite plug and a composite block.

Intended Use

NovaBone MacroFORM devices are intended to be used to fill bony defects in the skeletal system. The device will be marketed with the following indications statement, which is equivalent to that of the primary predicate, NovaBone Porous (K090731/K060432). The only difference is addition of the last sentence to emphasize the requirement for rigid fixation. MacroFORM does not include spine indications like the reference predicate (K083033, Vitoss) as MacroFORM will not be marketed for such uses. Therefore, no new issues of safety or effectiveness are presented when NovaBone MacroFORM is used for the following indications, as labeled:

510(k) SUMMARY
MacroFORM BIOACTIVE

DRIVING INNOVATION IN OSTEOBIOLOGICS

MacroFORM - Indications for Use:

> NovaBone MacroFORM bone graft devices are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone MacroFORM is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NovaBone MacroFORM must be hydrated with autogenous bone marrow prior to implantation. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Technological Characteristics and Substantial Equivalence

NovaBone MacroFORM and the predicate devices utilize biocompatible materials that fill bony voids and provide an environment for bone regeneration. The host bone remodels through an osteoconductive process as new bone grows into the porous matrix of the graft materials. The graft materials are slowly resorbed and replaced by the host bone. The proposed and predicate devices are not intended to be load bearing and are only intended to be used in defects that are not intrinsic to the stability of the bony structure. MacroFORM and the predicates have similar mode of action, therefore no new issues of safety or effectiveness are presented.

MacroFORM and the primary predicate (NovaBone Porous, K090731) incorporate the same bioactive component, a three-dimensional porous structure comprised of Bioglass® 45S5, an inorganic calcium phospho-silicate, which conforms to ASTM F1538-03. For both devices, the Bioglass particles are compressed and heated to form a porous mass. Therefore, no new issues of safety or effectiveness are raised by the bioactive agent in the proposed MacroFORM devices.

MacroFORM includes a handling agent derived from bovine collagen; however, the primary predicate, NovaBone Porous (K090731) is 100% Bioglass (without a handling agent). Biocompatibility testing demonstrates that MacroFORM materials do not raise new issues of biocompatibility safety.

Functional *in vivo* testing in an animal model (rabbit tibia defect) was performed on MacroFORM using the primary predicate (K090731, NovaBone Porous) as a control. The results demonstrate that bone remodeling process for MacroFORM is equivalent to that of NovaBone Porous. Therefore, no new issues of safety or effectiveness are raised by the *in vivo* performance of MacroFORM.

510(k) SUMMARY
MacroFORM BIOACTIVE

The bovine collagen used for the production of MacroFORM devices is obtained from a single source in Australia. Australia is recognized by the World Organization for Animal Health (OIE) to be free of BSE and other similar TSE pathogens. Australia also is termed a Geographical BSE Risk I, or GBR I country. The GBR I designation is the lowest risk rating, indicating the potential for one or more animals to infected with BSE agents as "Highly Unlikely". The processing steps used for the bovine collagen constituent for MacroFORM have viral inactivation benefits. Therefore, no new issues of safety or effectiveness are presented by the collagen source for MacroFORM.

Like the predicate devices, MacroFORM is supplied as a single-use sterile implantable graft, with double-barrier packaging. The device is sterilized to a sterility assurance level (SAL) of 10^{-6} using an irradiation method.

The processing and packaging methods employed to ensure biological safety of the finished device demonstrate that no new safety issues are raised for MacroFORM as compared to the predicate devices.

Conclusion

NovaBone MacroFORM BIOACTIVE is similar to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided for this premarket notification supports substantial equivalence to the primary predicate device, NovaBone Porous (K090731/K060432), with reference to Vitoss (K083033), for the bovine collagen constituent.

In vivo performance testing (rabbit tibia defect model) and biocompatibility testing were conducted in accordance with the "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device," June 2, 2003. Passing biocompatibility testing demonstrates MacroFORM BIOACTIVE devices are safe for implantation. In the rabbit tibia study MacroFORM BIOACTIVE performed in an equivalent manner to NovaBone Porous, the primary predicate.

Therefore, NovaBone MacroFORM BIOACTIVE bone void fillers are substantially equivalent to the NovaBone Porous predicate device (K090731/K060432).